

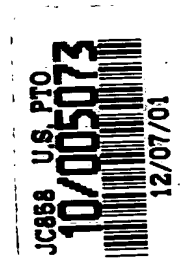
JC858 U.S. PTO  
 10/005073  
 12/07/01

**Examiner:** Unassigned

(10/01)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of	)	
	)	
Anthony M. JEVNIKAR et al.	)	Group Art Unit: Unassigned
	)	
Application No.: Unassigned	)	Examiner: Unassigned
	)	
Filed: December 7, 2001	)	
	)	
For: METHODS AND PRODUCTS FOR	)	
CONTROLLING THE IMMUNE	)	
RESPONSES IN MAMMALS	)	
	)	



**INFORMATION DISCLOSURE STATEMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98.

Copies of the below listed documents were previously submitted or cited in prior Application Serial No. 08/617,874, filed May 21, 1996, upon which Applicants rely for the benefits provided in 35 U.S.C. § 120. In accordance with 37 C.F.R. § 1.98(d), copies of the below listed documents are not included.

**U.S. PATENTS**

1. Lernmark et al., U.S. Patent No. 5,792,620, issued on August 17, 1993.
2. Lam et al., U.S. Patent No. 5,484,710, issued on August 26, 1991.
3. Tobin et al., U.S. Patent No. 5,475,086, issued on July 18, 1991.
4. Weiner et al., U.S. Patent No. 5,643,868, issued on October 10, 1990.
5. Lam et al., U.S. Patent No. 5,484,719, issued on January 16, 1996.

**FOREIGN PATENTS**

1. Lam et al., International Publication No. WO 94/20135, published September 15, 1994.
2. Rogers, International Publication No. WO 90/01551, published February 22, 1990.

3. Weiner et al., International Publication No. WO 92/07581, published May 14, 1992.
4. Weiner et al., International Publication No. WO 88/10120, published December 29, 1988.
5. Weiner et al., International Publication No. WO 92/06708, published April 30, 1992.
6. Autoimmune, Inc., International Publication No. WO 91/12816, published September 5, 1991.
7. Erlander et al., International Publication No. WO 92/05446, published April 2, 1992.
8. Hein et al., International Publication No. WO 91/06320, published May 16, 1991.

#### **OTHER DOCUMENTS**

1. Ma et al., "Transgenic plants expressing autoantigens fed to mice to induce oral immune tolerance," *Nature Medicine*, 1977, pp. 793-96, vol. 3, no. 7, Nature Publishing Company, New York, New York.
2. De Neve et al., "Assembly of an antibody and its derived antibody fragment in *Nicotiana* and *Arabidopsis*," *Transgenic Research*, 1993, pp. 227-37, vol. 2, Kluwer Academic Publishers, Dordrecht, Netherlands.
3. Nihara et al., *Eur. S. Immunol.*, 1996, p. 1736, vol. 26.
4. Lamb et al., "The effects of changes at peptide residues contacting MHC class II T-cell receptor on antigen recognition and human Th0 cell effector function," *Immunology*, 1995, pp. 447-54, vol. 85, no. 3, Blackwell Scientific Publications, Oxford, England.
5. McFarland et al., "Complexities in the treatment of autoimmune disease," *Science*, 1996, pp. 2054-07, vol. 274, American Association for the Advancement of Science, Washington, D.C.

6. Zhang et al., "Suppression of diabetes in nonobese diabetic mice by oral administration of porcine insulin," *Proc. Natl. Acad. Sci.*, 1991, pp. 10252-56, vol. 88, National Academy of Sciences, Washington, D.C.
7. Kay et al., "The immunological consequences of feeding cholera toxin II. Mechanisms Responsible for the Induction of Oral Tolerance for DTH," *Immunology*, 1989, pp. 416-21, vol. 66, Blackwell Science, Ltd., Malden, Maine.
8. Carrington et al., "Cap-Independent Enhancement of Translation by a Plant Potyvirus 5' Nontranslated Region," *Journal of Virology*, 1990, pp. 1590-97, vol. 64, no. 4, American Society for Microbiology, Washington, D.C.
9. Peng et al., "The generation of a 'tolerogen' after the ingestion of ovalbumin is time-dependent and unrelated to serum levels of immunoreactive antigen," *Clin. Ex. Immunol.*, 1990, pp. 510-15, vol. 81, American Association of Immunologists, Bethesda, Maryland.
10. Lamont et al., "Priming of systemic and local delayed-type hypersensitivity responses by feeding low doses of ovalbumin to mice," *Immunology*, 1989, pp. 595-99, vol. 66, Blackwell Science, Ltd., Malden, Maine.
11. Thompson et al., "Could specific oral tolerance by a therapy for autoimmune disease?" *Immunology Today*, 1990, pp. 396-99, vol. 11, no. 11, Blackwell Science, Ltd., Malden, Maine.
12. Weiner et al., "Double-Blind Pilot Trial of Oral Tolerization with Myelin Antigens in Multiple Sclerosis," *Science*, 1993, pp. 1321-24, vol. 259, American Association for the Advancement of Science, Washington, D.C.
13. Sayegh et al., "Induction of immunity and oral tolerance with polymorphic class II major histocompatibility complex allopeptides

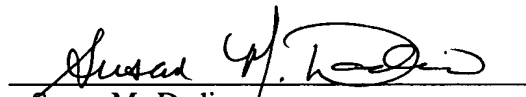
- in the rat," *Proc. Natl. Acad. Sci.*, 1992, pp. 7762-66, vol. 89, National Academy of Sciences, Washington, D.C.
14. Sayegh et al., "Oral Administration of Polymorphic Class II MHC Peptides Down-Regulates the Specific Cell Mediated Immune Responses in the Rat," *JASN (Abstract)*, 1991, p. 787 (57P), vol. 2.
  15. Trudel et al., "Expression of active hen egg white lysozyme in transgenic tobacco," *Plant Science*, 1992, pp. 55-67, vol. 87, Elsevier Science, New York, New York.
  16. Düring et al., "Synthesis and self-assembly of a functional monoclonal antibody in transgenic *Nicotiana tabacum*," *Plant Molecular Biology*, 1990, pp. 281-93, vol. 15, Kluwer Academic Publishers, Belgium.
  17. Swain, "Antibodies in plants," *TIBTECH*, 1991, pp. 107-09, vol. 9, Elsevier Science Publishers, Ltd., UK.
  18. Mason et al., "Expression of hepatitis B surface antigen in transgenic plants," *Proc. Natl. Acad. Sci. USA*, 1992, pp. 11745-49, vol. 89, National Academy of Sciences, Washington, D.C.
  19. Zambryski, "Basic Processes Underlying Agrobacterium-Mediated DNA Transfer to Plant Cells," *Annu. Rev. Genet.*, 1988, pp. 1-30, vol. 22, HighWire Press, Palo Alto, California.
  20. Horsch et al., "A Simple and General Method for Transferring Genes into Plants," *Science*, 1985, pp. 1229-31, vol. 227, American Association for the Advancement of Science, Washington, D.C.
  21. Harrison, "Islet cell antigens in insulin-dependent diabetes: Pandora's box revisited," *Immunology Today*, 1992, pp. 348-52, vol. 18, no. 9, Blackwell Science, Ltd., Malden, Maine.
  22. Tisch et al., "Immune response to glutamic acid decarboxylase correlates with insulinitis in non-obese diabetic mice," *Nature*, 1993, pp. 72-75, vol. 366, Nature Publishing Group, England.

23. Datla et al., "A bifunctional fusion between  $\beta$ -glucuronidase and neomycin phosphotransferase: a broad-spectrum marker enzyme for plants," *Gene*, 1991, pp. 239-46, vol. 101, Elsevier, New York, New York.
24. Sijmons et al., "Production of Correctly Processed Human Serum Albumin in Transgenic Plants," *Biotechnology*, 1990, pp. 217-21, vol. 8, Horizon Scientific Press, Norfolk, UK.
25. Lider et al., "Suppression of Experimental autoimmune encephalomyelitis by oral administration of myelin basic protein," *Journal of Immunology*, 1989, pp. 748-52, vol. 142, American Association of Immunologists, Bethesda, Maryland.
26. Brod et al., "Suppression of experimental autoimmune encephalomyelitis by oral administration of myelin antigens: IV. Suppression of chronic relapsing disease in the Lewis Rat and Strain 13 Guinea Pig," *Annals of Neurology*, 1991, pp. 615-22, vol. 29, Annual Reviews, Palo Alto, California
27. Hiatt et al., "Assembly of Antibodies and Mutagenized Variants in Transgenic Plants and Plant Cell Cultures," *Genetic Engineering*, 1992, pp. 49-64, vol. 14, Mary Ann Liebert, Inc., Larchmont, New York.
28. Hancock et al., "Prevention of Accelerated Allograft Rejection by Oral Administration of Alloantigen is associated with Selective Inhibition of TH1-Like Cell Function," *JASN (Abstract)*, 1991, p. 782 (8P), vol. 2.

To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By:   
Susan M. Dadio  
Registration No. 40,373

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(703) 836-6620

Date: December 7, 2001